IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

ABBOTT LABORATORIES,	)	
	)	
	)	
Plaintiff,	)	Case No. 05 C 6561
v.	)	
	)	Judge Virginia M. Kendall
MYLAN PHARMACEUTICALS, INC.,	)	
	)	
Defendant.	)	
	)	

MEMORANDUM OPINION AND ORDER

Plaintiff Abbott Laboratories ("Abbott") has brought suit against Defendant Mylan Pharmaceuticals, Inc., ("Mylan") for patent infringement on two patents for the pharmaceutical compound Depakote ER. Mylan filed several counterclaims, one of which seeks a declaratory judgment that six other patents used in the manufacture of Depakote ER, all patents for the formulation of the drug, are invalid. Abbott moved to dismiss Mylan's declaratory judgment counterclaim for lack of subject matter jurisdiction. Because the declaratory judgment claim does not present a case or controversy, Abbott's motion to dismiss is granted.

I. Background

A. *Background of the Generic Drug Approval Process*

The Federal Food, Drug, and Cosmetic Act of 1938, 21 U.S.C. §§ 1 *et seq.*, controls the procedures used by the Food and Drug Administration ("FDA") for the approval of generic drugs. In 1984, Congress substantially revised the original generic drug application and approval process through the Drug Price Competition and Patent Term Restoration Act of 1984, known as the "Hatch-Waxman Act." In 2003, Congress again modified the generic drug approval process through the

Medicare Prescription Drug Improvement and Modernization Act of 2003, known as the "Medicare Amendments."

In order to obtain approval to sell a pioneer drug, a drug manufacturer must file a detailed New Drug Application ("NDA") with the FDA. *See* 21 U.S.C. §§ 355(a)-(b). After the FDA has approved the NDA, the FDA lists the drug and patents that are used in the manufacture of the drug on a list called "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly referred to as the "Orange Book." 21 C.F.R. §314.3.

After a pioneer drug is listed in the Orange Book, a generic manufacturer may file an application to produce a generic version of the pioneer drug. A generic manufacturer submits an Abbreviated New Drug Application ("ANDA"), which may rely on the safety and efficacy studies in the NDA, but must show that the generic drug will be the bioequivalent of the pioneer drug. 21 U.S.C. § 355(j)(2)(A). As part of the ANDA, the generic manufacturer seeking approval must address each of the patents that are listed in the Orange Book, and must certify that the generic drug relates to each of the patents in one of four ways:

> (I) that such patent information has not been filed, (II) that such patent has expired, (III) of the date on which the patent will expire, or (IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted.

21 U.S.C. §§ 355(j)(2)(A)(vii). "These are commonly referred to as paragraph I, II, III, and IV certifications." *Teva Pharms. USA, Inc. v. Pfizer, Inc.*, 395 F. 3d 1324, 1328 (Fed. Cir. 2005).

A generic manufacturer must wait until a patent has expired before it may market a generic drug, unless the generic manufacturer files a paragraph IV certification. Upon filing a paragraph IV certification, the generic manufacturer is required to give notice to the patent holder and the NDA

holder of each patent that has been challenged and the factual and legal basis for the opinion that the patent is either invalid or will not be infringed. 21 U.S.C. §§ 355(j)(2)(B)(i), (iv).

Filing an ANDA with a paragraph IV certification, followed by notice to the patent holder and NDA holder, triggers a 45-day period during which the patent holder or NDA holder may file suit for patent infringement. 21 U.S.C. § 355(j)(5)(B)(iii). If the patent holder files suit for patent infringement within 45 days, the FDA may not approve the ANDA until the patent expires, the patent is found to be invalid or not infringed, or 30 months passes, whichever occurs first. *Id.* If the patent holder does not sue within those 45 days, the FDA may approve the ANDA immediately. *Id.*

The Hatch-Waxman Act creates an incentive for generic manufacturers to file paragraph IV certifications challenging the patents on pioneer drugs by providing a 180-day period of exclusive market access on the new generic drug to the first generic manufacturer to file a complete ANDA with a paragraph IV certification on a certain drug. 21 U.S.C. § 355(j)(5)(B)(iv). The FDA will not approve another generic manufacturer's ANDA for market until the 180-day period runs for the first paragraph IV filer. *Id.*

If an ANDA holder is the first to file a paragraph IV certification for a drug, that holder will get the exclusivity period regardless of whether (i) the patent expires; (ii) a court rules the patent invalid or not infringed, or (iii) the ANDA is approved immediately because the patentee did not file suit. However, the exclusivity period may be triggered earlier than anticipated should another generic company file an additional ANDA with a paragraph IV certification, and then succeed in obtaining a court ruling that the patent is invalid or not infringed. 21 U.S.C. § 355(j)(5)(B)(iii). The opportunity to trigger the 180-day exclusivity period early provides an incentive to all generic companies to continue to challenge the validity of a patent on a pioneer drug.

The Medicare Amendments of 2003 added a civil enforcement provision to be used by generic applicants in order to challenge the validity of patents. 21 U.S.C. §355(j)(5)(C). If neither the patent holder nor the NDA holder elect to file suit within 45 days, and the ANDA holder agrees to provide confidential access to information about the application, the statute provides that the ANDA applicant may bring an affirmative action for declaratory judgment that the patent is invalid or is not infringed in accordance with the Declaratory Judgment Act, 28 U.S.C. § 2201. *See* 21 U.S.C. § 355(j)(5)(C). It is this portion of the Hatch-Waxman Act that Mylan seeks to employ to bring a counterclaim for declaratory judgment.

B. Background to the Dispute

The parties do not dispute the facts in the pleadings relevant to a determination of subject matter jurisdiction. Abbott is the NDA holder for Depakote ER, an extended-release drug. In the Orange Book, Abbott lists a number of patents related to the manufacture of Depakote ER: both patents for the chemical compounds forming the active ingredients in the drug, and patents for the formulation of the drug to create the drug's "extended-release" effect. *See* Abbott Mot. Dis. at Ex. A. The Orange Book contains two patents for the chemical compounds in the drug, Patent Nos. 4,988,731 and 5,212,326 ("Compound Patents"), and six patents for formulation of the drug, Patent Nos. 6,419,953; 6,511,678; 6,528,090; 6,528,091; 6,713,086; and 6,720,004 (the "Formulation Patents").

In April 2005, Mylan filed an ANDA to manufacture a generic version of Depakote ER. As part of the ANDA, Mylan filed a paragraph III certification for the Compound Patents, set to expire in January 2008, and a paragraph IV certification for the Formulation Patents, set to expire in December 2018. *See* Abbott Mot. Dismiss at Ex. A. Mylan Opp. at 2. As required by the Hatch-

Waxman Act, Mylan sent notification to Abbott that it had filed a paragraph IV certification as to the Formulation Patents. Abbott did not file suit for patent infringement within the 45-day period permitted by the Hatch-Waxman Act. Abbott sent a letter to Mylan in May 2005 stating that it would not offer an opinion as to whether the product in the ANDA would infringe the Formulation Patents and expressly reserving all rights under any of Abbott's patents, including all claims for infringement. *See* Abbott Mot. to Dismiss at Ex. C.

In October 2005, Mylan amended its ANDA to file paragraph IV certification with respect to the Compound Patents (previously certified as paragraph III). Since the new paragraph IV certification triggered another 45-day period to file suit, Abbott filed suit for patent infringement on the Compound Patents only. To date, Abbott has not filed suit against Mylan, or any other company, with respect to the Formulation Patents. Mylan pleads a counterclaim for declaratory judgment on the Formulation Patents as part of the pending suit on the Compound Patents. As required by the Hatch-Waxman Act, Mylan sent Abbott an offer of confidential access to the information contained in its ANDA filing. Abbott Mot. Dismiss at Ex. D.

II. Analysis

A. Legal Standard

Federal Rule of Civil Procedure 12(b)(1) provides that a case will be dismissed if the court lacks the statutory authority to hear and decide the merits of a dispute. The standard of review for a motion to dismiss under Rule 12(b)(1) depends on the purpose of the motion. *See United Phosphorous, Ltd. v. Angus Chem. Co.*, 322 F.3d 942, 946 (7th Cir.2003) (*en banc*). In this case, the motion to dismiss challenges the face of the counterclaim rather than the facts of the counterclaim; the parties do not dispute the relevant facts contained in the counterclaim. If subject

matter jurisdiction is not evident from the face of the complaint, the court analyzes the motion to dismiss under Rule 12(b)(1) as any other motion to dismiss. *Id*. Therefore, the court must accept the facts as alleged in the counterclaim and draw all reasonable inferences in favor of the counter-claimant. *Sprint Spectrum L.P. v. City of Carmel, Indiana*, 361 F.3d 998, 1001 (7th Cir. 2004)

B. Declaratory Judgment

Mylan seeks to bring its counterclaim under The Declaratory Judgment Act, 28 U.S.C. § 2201(a). Specifically, Congress authorized the use of the Declaratory Judgment Act to permit generic manufacturers to seek declaratory judgments in circumstances such as the one before the Court, where a generic manufacturer filed a Paragraph IV certification and the patentee did not exercise its right to file suit for patent infringement within 45 days. *See* 21 U.S.C. §355(j)(5)(C).

The Declaratory Judgment Act states: "in a case of actual controversy within its jurisdiction . . . any court of the United States, upon the filing of an appropriate pleading, may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought." 28 U.S.C. § 2201(a). The "actual controversy" requirement in the Declaratory Judgment Act embodies the jurisdictional requirements found in Article III of the Constitution. *Teva Pharmaceuticals USA, Inc. v. Pfizer, Inc.*, 395 F.3d 1324, 1331 (Fed. Cir. 2005).

An "actual controversy" within the Act depends on "whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *Id.* at 1331, *quoting Md. Cas. Co. v. Pac. Coal & Oil Co.*, 312 U.S. 270, 273 (1941). "When there is no actual controversy, the court has no discretion to decide the case. When there is an actual

controversy and thus jurisdiction, the exercise of that jurisdiction is discretionary." *Teva* 395 F.3d at 1332, *quoting Spectronics Corp. v. H.B. Fuller Co.*, 940 F.2d 631, 634 (Fed. Cir. 1991).

The Federal Circuit affirmed a two-party inquiry into whether an actual controversy exists in a suit seeking a declaratory judgment of patent non-infringement or invalidity:

> There must be both (1) an explicit threat or other action by the patentee which creates a reasonable apprehension on the part of the declaratory judgment plaintiff that it will face an infringement suit; and (2) present activity by the declaratory judgment plaintiff which could constitute infringement, or concrete steps taken with the intent to conduct such activity.

Teva, 395 F.3d at 1332. When the defendant's conduct and statements "fall short of an express charge, one must consider the 'totality of the circumstances' in determining whether that conduct meets the first prong of the test." *Teva*, 395 F.3d at 1324, *quoting Arrowhead Indus. Water, Inc. v. Ecolochem, Inc.*, 846 F.3d 731, 736 (Fed. Cir. 1998).

In *Teva v. Pfizer*, the Federal Circuit discussed the application of this two-part test to a declaratory judgment action filed in the context of an ANDA application containing a paragraph IV certification in which the patentee Pfizer did not sue for infringement within the 45-day period set forth in the Hatch-Waxman Act. When the generic manufacturer Teva filed a declaratory judgment action, the Federal Circuit affirmed the district court's dismissal for lack of subject matter jurisdiction because Teva could not satisfy the requirements of the above test. The *Teva* court, following *Maryland Casualty*, distinguished the presence of "adverse legal interests" from a "reasonable apprehension" by looking to whether the controversy was of "sufficient immediacy," namely whether it was concrete and "actual or imminent, not conjectural or hypothetical." *Id*. at 1334, *quoting Maryland Casualty*, 312 U.S. at 273; *Steel Co. v. Citizens for a Better Environment*, 523 U.S. 83, 101 (1998).

While Mylan urges this Court that the two-part test in *Teva* need not be applied in every circumstance involving the Hatch-Waxman Act, and indeed urges that the test itself may unduly constrict the constitutional requirements for jurisdiction over a declaratory judgment action, this Court is bound by the precedent of the Federal Circuit. *See Foster v. Hallco Mfg. Co.*, 947 F.2d 469, 475 (Fed. Cir. 1991) (district courts must follow Federal Circuit precedent in cases arising under patent laws). The *Teva* court found by a two-to-one majority that the two-part test affirmed in *Teva* is not merely a prudential requirement that Congress could override through amendments to the Hatch-Waxman Act. *Teva*, 395 F.3d at 1335. The *Teva* court also specifically addressed the Medicare Amendments, and determined that declaratory judgment actions brought pursuant to the amended statute still needed to comply with the two-part test. *Id.* at 1336. Therefore, this Court is bound to apply the two-part test in *Teva* to the facts of this particular matter.[1]

The parties agree that Mylan fulfilled step two of the above two-part test when it filed an ANDA containing a paragraph IV certification that it believed the Formulation Patents were invalid and expressly notified Abbott of its opinion in letters to Abbott in April and October 2005. Therefore, the sole issue before the court is whether Abbott's actions have created a "reasonable apprehension" of an infringement suit.

B. Analysis of Mylan's "Reasonable Apprehension"

Mylan argues that unlike the generic applicant in *Teva*, the facts of this case meet the test for "reasonable apprehension" that Abbott will sue Mylan for patent infringement on the Formulation

[1]As Mylan conceded, many of the arguments made by Mylan in its opposition to Abbott's motion to dismiss parallel the dissenting opinion offered by two judges of the Federal Circuit when the Federal Circuit declined to rehear *Teva en banc*. *See Teva Pharmaceuticals USA, Inc. v. Pfizer, Inc.*, 405 F.3d 990 (Fed. Cir. 2005) (denying petition for rehearing).

Patents. Mylan believes that several aspects of this case distinguish the present circumstances from those in *Teva*: (i) Mylan brings the declaratory judgment action as a counterclaim to Abbott's patent infringement action on the Compound Patents, making suit imminent and already injurious to Mylan; (ii) Abbott has expressly reserved its rights to sue on the Formulation Patents; and (iii) Mylan has already been injured by Abbott's strategic decision to sue on only some of the patents. Mylan Opp. at 8, 10-12, 11 n.6. Upon consideration of these circumstances in light of *Teva*, the Court finds that Mylan's arguments do not create a reasonable apprehension of suit to confer jurisdiction over the counterclaim.

1. Mylan's suit as counterclaim to an ongoing proceeding

Mylan distinguishes the facts in *Teva* from the facts before the Court because Mylan brings suit for declaratory judgment on the Formulation Patents as a counterclaim to a suit brought by Abbott on the Compound Patents. Since Mylan filed a paragraph IV certification for both the Formulation Patents and the Compound Patents in the same ANDA, Mylan argues that it has a reasonable apprehension of suit by Abbott on the Formulation Patents because "the existence of a dispute between the parties is not theoretical and of *some degree of imminence*, but exists in fact and is current." Mylan Opp. at 10. But the dispute between the parties at present is a dispute over the validity of the Compound Patents; the link between the Compound Patents and the Formulation Patents is the fact that the patents are all listed by Abbott in the Orange Book under its entry for Depakote ER.

The fact that the Compound Patents and the Formulation Patents are both listed in the Orange Book does not escape the reality that Abbott has never made a threat or taken any action that indicates an intent to sue Mylan - or any other generic manufacturer - over the Formulation Patents.

As has been discussed in *Teva* and in district opinions preceding and following *Teva*, the mere fact that a patent is listed alongside other patents in the Orange Book is not sufficient to indicate a reasonable apprehension of suit. *See Teva*, 395 F.3d at 1333 ("The Orange Book is a listing of patents with respect to which claims of infringement '*could* be reasonably asserted. . . More is required for an actual controversy than the existence of an adversely held patent, however.") (citations omitted); *Mylan Pharmaceuticals Inc. v. Merck & Co., Inc.*, 2005 WL 2850137 at * 5 (M.D. Pa. Oct. 28, 2005) ("The Orange Book listing is insufficient to satisfy the objective intent to sue standard required to establish an actual controversy . . ."); *Apotex, Inc. v. Pfizer, Inc.*, 385 F. Supp. 2d 187, 194 (S.D.N.Y. 2005) ("An Orange Book listing imposes no obligation on the patent owner to sue, and does not suggest that a suit is expected or even likely.")

Indeed, when viewing the totality of the circumstances, the facts as presented to the Court show that Abbott's actions at this time are more suggestive of its intent not to file imminent suit on the Formulation Patents. Abbott had the opportunity to sue on the Formulation Patents in April 2005, when Mylan first submitted an ANDA containing a paragraph IV certification on the Formulation Patents, but Abbott permitted the 45-day period to pass without filing suit. Then, when Mylan changed its certification of the Compound Patents from paragraph III to paragraph IV in October 2005, Mylan provided second notice of the infringement on the Formulation Patents. Abbott made the decision to sue on the Compound Patents, but again opted not to sue on the Formulation Patents.

In this sense, this case bears factual resemblance to another recent declaratory judgment case over this same statutory provision, *Teva Pharm. Inc. v. Novartis Pharm. Corp.* 2005 WL 3619389 (D. N.J. Dec. 12, 2005). In *Teva v. Novartis*, Teva was the first generic company to file an ANDA

for an extended release drug. The ANDA contained paragraph IV certifications for five patents, one compound patent and four method patents. The patentee Novartis sued for infringement of one the one compound patent, but allowed the 45-day window to pass on the four method patents. Teva brought a separate, simultaneous declaratory judgment action in same district as the patent infringement suit filed by Novartis. *Novartis* at *1. In order to distinguish the case from the adverse precedent of the Federal Circuit's *Teva* decision, Teva in this action argued that - like Abbott and Mylan before this Court - Novartis had already filed suit on other patents in the same ANDA. The *Novartis* court found that the ongoing suit weakened Teva's argument that it had reasonable apprehension of future suit on the method patents, since Novartis could have sued on the four method patents at that time but chose not to do so. Likewise, in this case Abbott had two opportunities to file suit on the Formulation Patents, and it still has not done so. The fact that Mylan brought the declaratory judgment action as a counterclaim rather than as a separate suit in the same district does not create a material distinction from the reasoning set forth in *Teva v. Novartis.*

2. Abbott's reservation of rights

Mylan also argues that Abbott has refused to give assurances that it will not sue Mylan in the future for patent infringement on the Formulation Patents, and has reserved its rights to assert some of the patents that are certified in Mylan's ANDA. Abbott, via letter to Mylan in May 2005, did not indicate that it would or would not sue for infringement of the Formulation Patents at some point in the future - Abbott reserved its rights. "Although a patentee's refusal to give assurances that it will not enforce its patent is relevant to the determination [of reasonable apprehension], this factor is not dispositive." *Teva*, 395 F.3d at 1333, *quoting BP Chems. Ltd. v. Union Carbide Corp.*, 4 F.3d 975, 980 (Fed. Cir. 1993).

This distinction, like the distinction of a counterclaim versus a separate suit, does not persuade the Court that this matter is factually distinguishable from the precedent of *Teva*. In *Teva*, the court was not persuaded that a generic manufacturer had a reasonable apprehension of suit because the patentee would not agree to sign a covenant not to sue. *Teva*, 395 F.3d at 1333. Abbott is not under a statutory obligation to choose between suing within 45 days or giving an assurance that it will not sue. *See Mylan v. Merck*, 2005 WL 2850137 at *8. There is nothing in the statutory authority that precludes Abbott from filing suit for infringement at some point in the future. The Court agrees with the court in *Mylan v. Merck* that Abbott's failure to sue and reservation of rights is too speculative an action to be a "concrete" injury rather than merely hypothetical. *Id.*

Abbott has substantively briefed the law surrounding the effect of its letter of May 2005. The Court need not, and does not, state any opinion as to the impact of Abbott's reservation of rights letter should Abbott eventually file suit for patent infringement on the Formulation Patents. That issue is not relevant to the determination of whether Mylan has a reasonable apprehension of suit at this time, and any ruling on the effects of such a letter in any hypothetical suit would be advisory and therefore inappropriate.

3. Mylan has been injured by Abbott's strategic decision not to sue

Finally, Mylan contends that Abbott has made a strategic decision to sue for infringement of the Compound Patents by invoking the 30-month stay of FDA approval of Mylan's ANDA for Depakote ER, yet simultaneously leaving open the possibility that it may sue Mylan again at a later date for infringement of the Formulation Patents. Therefore, argues Mylan, it suffers present injury from the 30-month stay, and should be able to bring a declaratory judgment action for the remaining patents rather than potentially face a subsequent suit over the Formulation Patents.

The Court will not speculate as to Abbott's reason for choosing not to file suit on the Formulation Patents. The relevant fact is that Abbott did not sue, and has not threatened to sue or taken action indicating suit. Without a reasonable apprehension that a suit is imminent, and not merely hypothetical, the court cannot exercise jurisdiction over a declaratory judgment action for non-infringement. *See Teva*, 395 F.3d at 1338. Should Abbott decide to sue over the Formulation Patents at any later date, the 30-month stay will not be available to protect Abbott while any subsequent patent infringement action is adjudicated. While it is apparent from the briefing that the *Teva* decision is frustrating to Mylan, and Mylan disagrees with both the outcome of that case specifically and potentially widespread impact of its holding, this Court is bound to follow the Federal Circuit precedent. The *Teva* court specifically addressed the relative business advantages to patentees and generic manufacturers that might flow from the court's holding and concluded that such questions "are matters separate and distinct from whether an Article III controversy exists." *Id.* It is not the court's responsibility "to address any perceived inequities in the statutory scheme by eliminating the reasonable apprehension of suit test in Hatch-Waxman cases." *Id.* Like the case before the court in *Teva*, the facts of Mylan's counterclaim for declaratory judgment before this Court do not present a case or controversy and must be dismissed for lack of jurisdiction.

So Ordered.

Virginia M. Kendall, United States District Judge
Northern District of Illinois

Date: June 13, 2006